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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,192	07/14/1999	ALAN GEORGE BAXTER	229752000600	5844

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/308,192	Applicant(s) BAXTER, ALAN GEORGE	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-19 and 22-25 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 11-19 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8-10 and 22-25 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANT'S AMENDMENT

Applicant's Amendment

- 1) Acknowledgment is made of Applicant's amendment filed 06/07/05 in response to the non-final Office Action mailed 12/07/04.

Status of Claims

- 2) Claims 1, 8 and 9 have been amended via the amendment filed 06/07/05.
New claims 23-25 have been added via the amendment filed 06/07/05.
Claims 1, 8-19 and 22-25 are pending.
Claims 1, 8-10 and 22-25 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

The Baxter Declaration

- 5) Acknowledgment is made of Applicant's submission of the Baxter Declaration filed 06/07/05. The declaration has been fully considered. The declaration states that a single dose of MAPG from either heat-killed *Mycobacterium tuberculosis* or heat-killed *Mycobacterium bovis* BCG injected intravenously to NOD/Lt mice which spontaneously develop IDDM prevented the development of diabetes. The declaration also states that additional experiments were performed in which 'a sub-component of MAPG' namely arabinogalactan peptidoglycan (APG, which is MAPG with the mycolic acids removed) was administered to NOD/Lt mice. The declaration further states that NOD/Lt mice injected with 'AGP' [sic] showed no diabetes.

Rejection(s) Withdrawn

- 6) The rejection of claim 1 made in paragraph 11 of the Office Action mailed 02/26/03 and

maintained in paragraph 13 of the Office Action mailed 09/16/03 and paragraph 10 of the Office Action mailed 12/07/04 under 35 U.S.C. § 102(a) as being anticipated by Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is withdrawn in light of Applicant's amendment to the claim.

7) The rejection of claims 1 and 10 made in paragraph 12 of the Office Action mailed 02/26/03 and maintained in paragraph 14 of the Office Action mailed 09/16/03 and paragraph 11 of the Office Action mailed 12/07/04 under 35 U.S.C. § 103(a) as being unpatentable over Stosic-Grujicic *et al.* (*Mikrobiologija* 33 (1): 27-36, 1996), is withdrawn in light of Applicant's amendment to the base claim.

8) The rejection of claims 1 and 9 made in paragraph 15(b) of the Office Action mailed 09/16/03 and maintained in paragraph 12 of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

9) The rejection of claims 8-10 made in paragraph 15(d) of the Office Action mailed 09/16/03 and maintained in paragraph 13 of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

10) The rejection of claims 1 and 8-10 made in paragraph 7 of the Office Action mailed 02/26/03 and maintained in paragraph 12 of the Office Action mailed 09/16/03 and paragraph 9 of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope, is withdrawn in light of Applicant's amendment to the base claim and claim 9.

11) The rejection of claim 1 made in paragraph 14(a) of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

12) The rejection of claim 8 made in paragraph 14(b) of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

13) The rejection of claim 9 made in paragraph 14(c) of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

14) The rejection of claim 1 made in paragraph 14(d) of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

15) The rejection of claims 8-10 made in paragraph 14(e) of the Office Action mailed 12/07/04 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

New Rejection(s) Based on Applicant's Amendment

Applicant is asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicant's amendments to the claims and/or submission of new claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

16) Claims 1, 8-10 and 24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claim 24 is vague and confusing in the limitation: 'claim 1, wherein MAPG or a component thereof', because claim 1 does not recite 'a component' of MAPG.

(b) Claim 24 lacks antecedent basis in the limitation: 'MAPG'. Claim 24 depends from claim 1, which already recites 'MAPG'. For proper antecedent basis, it is suggested that Applicant replace the limitation with --said MAPG--.

(c) Claim 1 is vague, indefinite, confusing and/or incorrect in the limitation 'arabinogalactin'. It is unclear in what way does mycolyl 'arabinogalactin' peptidoglycan differ from mycolyl 'arabinogalactan' peptidoglycan that is recited in claim 23.

(d) Claims 8-10 and 24, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

17) Claims 23, 24 and 25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stanford *et al.* (WO 91/02542) as evidenced by Engelmayer *et al.* (US 20050004006).

It is noted that the active element(s) recited in the claims, i.e., one or more components MAPG selected from the group consisting of mycolic acids, peptidoglycan, or arabinogalactan, are not required to be purified. Although claim 24 depends from claim 1, claim 1 is not included in this rejection since claim 1 does not recite 'a component' of MAPG.

Stanford *et al.* disclosed a method of immunomodulatory treatment of primary diabetes mellitus (i.e., IDDM) in a patient comprising administering to the patient an effective amount of a therapeutic composition comprising an antigenic and immunoregulatory material, or an extract or fractionated portion derived from *Mycobacterium vaccae* (see pages 3, 2 and 7; and claims 1, 7, 9 and 11). The prior art method anticipates the instant claims. The therapeutic composition used in Stanford's method comprising an antigenic and immunoregulatory material, an extract or fractionated portion, derived from *Mycobacterium vaccae*, is expected to inherently contain one or more of mycolic acids, peptidoglycan, or arabinogalactan components thereof. That the primary diabetes mellitus treated in the prior art method includes IDDM is inherent from the teachings of Stanford *et al.* in light of what is well known in the art. For instance, Engelmayer *et al.* teach that insulin-dependent diabetes mellitus (IDDM) is primary diabetes mellitus (see paragraph 0030).

Claims 23, 24 and 25 are anticipated by Stanford *et al.* The reference of Engelmayer *et al.* is **not** used as a secondary reference in combination with the reference of Stanford *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Stanford *et al.* with the unrecited limitation(s) being inherent as evidenced by the state of the art. See *In re Samour* 197 USPQ 1 (CCPA 1978).

18) Claim 23 is rejected under 35 U.S.C. § 102(b) as being anticipated by Chugh *et al.* (*Folia Microbiol.* 37: 407-412, 1992).

The limitation in claim 23: 'for the treatment of insulin-dependent diabetes mellitus (IDDM)' represents the intended use of the claimed method and is of no significance to claim construction. A recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The recitation 'for the treatment of insulin-dependent diabetes mellitus (IDDM)' is merely a recitation of the purpose or the intended use of the process. The body of the claim does not depend on this limitation for completeness but, instead, the process step or structural limitation is able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The only structural element of the claimed process of claim 23 that needs to be met by the prior art is a method of immunomodulatory therapy in a mammal said method comprising administering to said mammal an immunomodulating effective amount of one or more components of MAPG selected from the group consisting of mycolic acids, peptidoglycan, or arabinogalactan isolated from the cell wall of *Mycobacterium*.

Chugh *et al.* taught a method of eliciting cell-mediated and humoral immune response (i.e., immunomodulation) in mice (i.e., mammals) comprising administering to mice 45 micrograms (i.e., an immunomodulating effective amount) of mycolic acids and arabinogalactans or CW-PPC, obtained from the cell-wall fractions of *M. tuberculosis* H37Ra. See abstract; page 37; and Table 3.

Claim 23 is anticipated by Chugh *et al.*

Remarks

19) Claims 1, 8-10 and 23-25 stand rejected.

20) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final

action.

21) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (571) 273-8300.

22) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

August, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER